Appln. No.: 10/577,840 TJA-139US

Amendment Dated December 23, 2008

Reply to Office Action of September 24, 2008

<u>Amendments to the Claims</u>: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. - 12. (Cancelled)

- 13. (Previously Presented) A method to obtain an immunotherapeutic agent that contains cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain of cells comprising the sequential steps of
 - a) culturing the cells for a period of at least three weeks and
 - b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds.
- 14. (Previously Presented) The method according to claim 13 wherein the cell culturing period ranges from 3 to 4 weeks.
- 15. (Previously Presented) The method according to claim 13 wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
- 16. (Previously Presented) The method according to claim 15 wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
- 17. (Previously Presented) The method according to claim 16 wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
- 18. (Previously Presented) The method according to claim 13 wherein the cells are homogenized in a buffered medium having a neutral pH.
- 19. (Previously Presented) The method according to claim 18 wherein the medium is buffered with PBS buffer.
- 20. (Previously Presented) An immunotherapeutic agent obtained by the method according to claim 13.
- 21. (Previously Presented) The method according to claim 13 further comprising the steps of

TJA-139US

Appln. No.: 10/577,840

Amendment Dated December 23, 2008

Reply to Office Action of September 24, 2008

c) centrifuging the homogenized cell mixture to separate the cell wall fragments from the non-fragmented cells and the solubilized cell compounds,

- d) washing the cell wall fragments and further treating the cell wall fragments to inactivate any remaining virulent cells, and
- e) lyophilizing the resulting immunotherapeutic agent.
- 22. (Previously Presented) The method according to claim 21 wherein the cell culturing period ranges from 3 to 4 weeks.
- 23. (Previously Presented) The method according to claim 21 wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
- 24. (Previously Presented) The method according to claim 23 wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
- 25. (Previously Presented) The method according to claim 24 wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
- 26. (Previously Presented) The method according to claim 21 wherein the cells are homogenized in a buffered medium having a neutral pH.
- 27. (Previously Presented) The method according to claim 26 wherein the medium is buffered with PBS buffer.
- 28. (Previously Presented) An immunotherapeutic agent obtained by the method according to claim 21.
- 29. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 13.
- 30. (Previously Presented) The pharmaceutical composition according to claim 29 in form of liposomes.
- 31. (Previously Presented) The pharmaceutical composition according to claim 30 wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.

TJA-139US

Appln. No.: 10/577,840

Amendment Dated December 23, 2008

Reply to Office Action of September 24, 2008

32. (Previously Presented) The pharmaceutical composition according to claim 30 wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.

- 33. (Previously Presented) The pharmaceutical composition according to claim 30 wherein the sterols are selected from cholesterol and biliar salts.
- 34. (Previously Presented) The pharmaceutical composition according to claim 30, further comprising vitamin E.
- 35. (Previously Presented) A method for the combined treatment of tuberculosis comprising administering the immunotherapeutic agent of claim 20 in combination with at least one drug suitable for the treatment of tuberculosis.
- 36. (Previously Presented) The method of claim 35 wherein the combined therapy is sequential or simultaneous.
- 37. (Previously Presented) The method of claim 35, wherein the drug is selected from the group consisting of isoniazid, rifampicin, and combinations thereof.
- 38. (Previously Presented) A pharmaceutical composition comprising the immunotherapeutic agent of claim 28.
- 39. (Previously Presented) The pharmaceutical composition according to claim 38 in form of liposomes.
- 40. (Previously Presented) The pharmaceutical composition according to claim 39 wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.
- 41. (Previously Presented) The pharmaceutical composition according to claim 40 wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.
- 42. (Previously Presented) The pharmaceutical composition according to claim 40 wherein the sterols are selected from cholesterol and biliar salts.
- 43. (Previously Presented) The pharmaceutical composition according to claim 39, further comprising vitamin E.

Appln. No.: 10/577,840 TJA-139US

Amendment Dated December 23, 2008
Reply to Office Action of September 24, 2008

44. (Previously Presented) A method for the combined treatment of tuberculosis comprising administering the immunotherapeutic agent of claim 28 in combination with at least one drug suitable for the treatment of tuberculosis.

- 45. (Previously Presented) The method of claim 44 wherein the combined therapy is sequential or simultaneous.
- 46. (Previously Presented) The method of claim 44, wherein the drug is selected from the group consisting of isoniazid, rifampicin, and combinations thereof.
- 47. (New) An immunotherapeutic agent comprising cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain of cells obtained by a process comprising the steps of:
 - a) culturing the cells for a period of at least three weeks, and
- b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds, wherein the non-ionic surfactant is selected from the group consisting of alkylphenol ethoxylates and ethoxylated sorbitan esters.
- 48. (New) The immunotherapeutic agent according to claim 47, wherein the cell culturing period ranges from 3 to 4 weeks.
- 49. (New) The immunotherapeutic agent according to claim 47, wherein the non-ionic surfactant is an octylphenol ethoxylate compound.
- 50. (New) The immunotherapeutic agent according to claim 49, wherein the non-ionic surfactant is an octylphenol ethoxylate having 7-8 mol of ethylene oxide.
- 51. (New) The immunotherapeutic agent according to claim 47, wherein the cells are homogenized in a buffered medium having a neutral pH.
- 52. (New) The immunotherapeutic agent according to claim 51, wherein the medium is buffered with PBS buffer.
- 53. (New) The immunotherapeutic agent according to claim 47, wherein the method further comprising the steps of:
- c) centrifuging the homogenized cell mixture to separate the cell wall fragments from the non-fragmented cells and the solubilized cell compounds,

TJA-139US

Appln. No.: 10/577,840

Amendment Dated December 23, 2008

Reply to Office Action of September 24, 2008

d) washing the cell wall fragments and further treating the cell wall fragments to inactivate any remaining virulent cells, and

- e) lyophilizing the resulting immunotherapeutic agent.
- 54. (New) A pharmaceutical composition comprising the immunotherapeutic agent of claim 47.
- 55. (New) A pharmaceutical composition comprising the immunotherapeutic agent of claim 53.
- 56. (New) The pharmaceutical composition according to claim 54, in the form of liposomes.
- 57. (New) The pharmaceutical composition according to claim 56, wherein the liposomes comprise auxiliary lipids selected from neutral and/or negatively charged phospholipids, and sterols.
- 58. (New) The pharmaceutical composition according to claim 57, wherein the phospholipids are selected from phosphatidylcholine, phosphatidylserine, and phosphatidylinositol.
- 59. (New) The pharmaceutical composition according to claim 58, wherein the sterols are selected from cholesterol and biliar salts.
- 60. (New) The pharmaceutical composition according to claim 59, further comprising vitamin E.